

FOOD AND DRUG ADMINISTRATION

Center for Drug Evaluation and Research

Joint Meeting of the Anti-Infective Drugs Advisory Committee and Nonprescription Drugs Advisory Committee

DoubleTree by Hilton Hotel Washington DC/Silver Spring
8727 Colesville Road, Silver Spring, Maryland

April 2, 2012

DRAFT QUESTIONS TO THE COMMITTEES

1. **DISCUSSION:** Please comment on the public health implications of a prescription doxycycline MedKit intended for post-exposure prophylaxis for an anthrax counterterrorism event. Specifically address potential benefits and risks if a prescription MedKit were approved with the intention of home storage.
2. **DISCUSSION:**
 - a. Please comment on additions or modifications to the proposed and/or completed studies (e.g. label comprehension, palatability, simulated use, or additional studies) that would help to assess the risks and benefits. What types of additional studies would be helpful to assess how users would behave in a real-life situation?
 - b. What is a reasonable percentage of study subjects who should understand the various components of the label and/or be able to refrain from using the product for other uses?
3. **DISCUSSION:** The doxycycline MedKit proposal includes instructions for dosing children and adults who cannot swallow pills using the 100 mg tablets. Please comment on any additional recommended studies to evaluate the dosing instructions in this population.
4. **DISCUSSION:** Doxycycline is available in other dosages and as liquid formulations. Please discuss the pros and cons of the home preparation mixture versus other available formulations for use in a MedKit.